

FAMILY WELLNESS ANTIFUNGAL- tolnaftate cream

Family Dollar

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

| Active Ingredient | Purpose |
|-------------------|---------|
|-------------------|---------|

| | |
|--------------------|------------|
| Tolnaftate 1%..... | Antifungal |
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Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot with daily use
- for effective relief of itching, burning, and cracking

Warnings

For external use only

When using this product avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

Do not use on children under 2 years of age except under the advice and supervision of a doctor

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wash affected area and dry thoroughly apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily
- use daily for 4 weeks; if conditions persist longer, ask doctor
- to prevent athlete's foot, apply once or twice daily (morning and/or night)
- this product is not effective on the scalp or nails

Other information

- store between 20°C to 25°C (68°F to 77°F)

Inactive ingredients

ceteth-20, cetostearyl alcohol, chlorocresol, liquid paraffin, monorask sodium phosphate dilhydrate, propylene glycol, purified water, white petrolatum

DISTRIBUTED BY:

FAMILY DOLLAR SERVICES INC.

10401 MONROE RD.

MATTHEWS, NC 28105 USA



FAMILY WELLNESS ANTIFUNGAL

tolnaftate cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55319-638 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | | | |
|--|---|-----------------------------|-----------------------------|---------------------------|
| TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) | | TOLNAFTATE | 1 g in 100 g | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| CETETH-20 (UNII: I835H2IHHX) | | | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | | | |
| CHLOROCRESOL (UNII: 36W53O7109) | | | | |
| PARAFFIN (UNII: I9O0E3H2ZE) | | | | |
| MAGNESIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: H3992158BT) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:55319-638-28 | 1 in 1 BOX | | |
| 1 | | 28 g in 1 TUBE | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part333C | 01/21/2014 | | |

Labeler - Family Dollar (024472631)

Revised: 1/2014

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